

**REMARKS**

Upon entry of the foregoing Amendment, claims 1-31, and 38 are pending in the application. Claims 1-31 and 38 have been amended. Claims 32-37 and 39-47 have been cancelled without prejudice or disclaimer. No new claims have been added. Applicant believes that one having ordinary skill in the art would find the amendments to the claims to be supported by the specification as filed.

In view of the foregoing Amendment and following Remarks, allowance of all the pending claims is requested.

**CLAIM OBJECTIONS**

Claims 9, 10, 14, 15, 17 and 31 have been objected to as allegedly containing certain informalities. Applicant traverses these objections for at least the reasons that the Examiner has not clearly articulated a basis for the objections. Rather, the Examiner merely suggests changes to the dependency of the claims objected to. Nevertheless, Applicant has amended claims 9, 10, 14, 15, 17 and 31 for other reasons, rendering the objection moot. Accordingly, withdrawal of the objections is requested.

**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

The Examiner has rejected claims 9 and 10 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner takes issue with the use of "help" and "tight" in claims 9 and 10 respectively. Applicant traverses this rejection as the claims, as originally filed, particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Nevertheless, solely for the purposes of expediting prosecution of the application, Applicant has removed any allegedly indefinite terms. Therefore, Applicant requests withdrawal of the rejection.

**REJECTION UNDER 35 U.S.C. §101**

The Examiner has rejected claims 21-47 under 35 U.S.C. §101 as allegedly directed towards non-statutory subject matter. Applicant traverses these rejections, because claims 21-47, as filed, are clearly directed towards statutory subject matter. However, without conceding the propriety of the rejection, and solely for the purposes of expediting prosecution of the application, Applicant has amended independent claims 21, 23, 24, 29, 30, and 38 to recite that the methods thereof are executed by one or more processors configured to perform a plurality of operations. Therefore, the rejection to claims 21, 23, 24, 29, 30, and 38 and all claims depending therefrom are improper and must be withdrawn. Claims 32-37 and 39-47 have been canceled without prejudice or disclaimer, rendering the rejection thereto moot.

**REJECTION UNDER 35 U.S.C. §102**

The Examiner has rejected claims 1-11, 13-20, 21, 22, and 32-47 under 35 U.S.C. §102(b) as allegedly anticipated by International Patent Application Publication No. WO01/093160 by Thangaraj et al. ("Thangaraj"). Applicants traverse this rejection for at least the reason that Thangaraj fails to disclose all of the features of the rejected claims. Nevertheless, solely for expediting prosecution of the application, Applicant has amended claim 1 to clarify the language thereof. Thangaraj fails to disclose all of the features of independent claim 1, as amended.

For example, claim 1, as amended, recites:

one or more processors configured to: \* \* \*

receive, from a user, protocol design information relating to design of a protocol for the at least one clinical trial,

interface with one or more third party standards databases to acquire standards information relevant to the protocol for the at least one clinical trial,

formulate the protocol using at least the design information and the standards information...

The Examiner alleges that Thangaraj discloses "a dictionary and standards component" that enables interface with relevant dictionaries and standards at page 24, ll. 5-14. See May 2009 Office Action, pg. 7. However, this portion of Thangaraj appears to describe a pipelined data

flow architecture, which discusses "input and output of information to and from external systems," but does not specifically disclose interface with third party standards databases to acquire standards information that is subsequently used to formulate clinical trial protocol. Rather, the system components discussed in this portion of Thangaraj apparently relate to a CDIP that provides predefined information processing. See Thangaraj, pg. 24, ll. 5-6. CDIP apparently refers to "clinical data interchange pipeline," and as such appears geared towards clinical data resulting from performing clinical trial actions and not to standards information from third party standards databases used to create a clinical trial protocol.

For at least these reasons, the Examiner has failed to show that Thangaraj discloses all of the features of claim 1, as amended. As such, the rejection of claim 1 is improper and must be withdrawn. Claims 2-11 and 13-20 each depend from and add features to claim 1. Therefore, for at least the reasons set forth above with respect to claim 1, the rejection of claims 2-11 and 13-20 are likewise improper and must be withdrawn.

Claim 21 recites: *"extracting data from at least one database related to the clinical trial based on the reporting requirements for the stakeholder."* The Examiner alleges that Thangaraj discloses extracting data from a system based on reporting requirements at pg. 10, ll. 8-14. May 2009 Office Action, at pg. 12. However, this portion of Thangaraj appears to merely relate to a discussion of use of the Internet and intranets to participants to communicate with each other, but does not discuss extraction of data based on reporting requirements, much less based on reporting requirements for a stakeholder. For at least this reason, the Examiner has failed to show that Thangaraj discloses all of the features of claim 21. Therefore, the rejection thereto is improper and must be withdrawn. Claim 22 depends from and adds features to claim 21. As such, the rejection thereto is likewise improper and must be withdrawn.

Claims 32-37 are cancelled without prejudice or disclaimer, rendering the rejection thereto moot. However, Applicant reserves the right to pursue these cancelled claims or claims as presented at any point during prosecution in one or more continuation or divisional applications, as the cancellation of claims and amendments to the claims made herein are solely for the purpose of expediting prosecution of the application.

Claim 38 recites: *"notifying at least one stakeholder associated with the clinical trial of completion of the clinical trial when the database has been locked."* The Examiner alleges that Thangaraj discloses providing a first report of treatment allocation for all enrolled subjects at pg. 23, ll. 28-34. See May 2009 Office Action, pg. 16. However, at best, this portion of Thangaraj appears to relate to notifications relating to data changes or clinical visits and locking individual patient data, but do not specifically relate to notifying a stakeholder of locking data much less notifying a stakeholder when an entire database of clinical trial data has been locked. In fact, the "notice" given in the portion of Thangaraj relied upon apparently relates to notification of data changes which emphasizes the fact that notification of data locking is not contemplated by the cited portion of Thangaraj. For at least these reasons, the Examiner has not shown that Thangaraj discloses all of the features of claim 38. Therefore, the rejection thereto is improper and must be withdrawn.

Claims 39-47 have been cancelled without prejudice or disclaimer, rendering the rejections thereto moot. However, Applicant reserves the right to pursue these cancelled claims or claims as presented at any point during prosecution in one or more continuation or divisional applications, as the cancellation of claims and amendments to the claims made herein are solely for the purpose of expediting prosecution of the application.

#### **REJECTION UNDER 35 U.S.C. §103**

The Examiner has rejected claim 12 under 35 U.S.C. §103(a) as allegedly being unpatentable in light of Thangaraj in view of U.S. Patent Application Publication No. 20040010418 by Buonocore et al. ("Buonocore"). Applicant traverses this rejection for at least the reason that the Examiner has failed to make a prima facie case of obviousness. For example, claim 12 depends from and adds features to claim 1. As discussed above, Thangaraj fails to disclose all of the features of claim 1. The Examiner's reliance on Buonocore fails to cure the deficiencies of Thangaraj. As such, for at least the reasons set forth above with respect to claim 1, the rejection of claim 12 is likewise improper and must be withdrawn.

The Examiner has also rejected claims 24-30 under 35 U.S.C. §103(a) as allegedly unpatentable in light of Buonocore. Applicants traverse this rejection for at least the reason that the Examiner has failed to make a prima facie case of obviousness. For example, claim 24 recites: *"generating a checklist of items related to a scheduled visit of the at least one subject; [and] documenting items from the checklist that are completed or not completed."* The Examiner alleges that Buonocore teaches generating a checklist upon a visit by the subject and documenting the checklist of completed and not completed items after the visit by the subject at ¶¶40 and 45. See May 2009 Office Action, pg. 20. However, while ¶40 may mention a survey or questionnaire to be taken by a trial participant, there is no teaching in these portions of Buonocore of documenting items that are completed or not completed. For at least this reason, the Examiner has failed to show that all of the features of claim 24 are taught by Buonocore.

Furthermore, the Examiner concedes that certain features of claim 24, 29, and 30 are not specifically disclosed by Buonocore. See May 2009 Office Action, pgs. 20, 22. The Examiner goes on to provide a subsequent list of certain aspects allegedly present in Buonocore. Id. This subsequent list of features do not include the features admittedly not present in Buonocore. However, the Examiner nevertheless concludes because Buonocore includes (allegedly) the subsequent list of features, that it would be obvious to include the features admitted not to be present in Buonocore "because doing so could be performed readily and easily by any person of ordinary skill in the art with neither undue experimentation, nor risk of unexpected results." See May 2009 Office Action, pg. 21. These statements by the Examiner illustrate that the Examiner has failed to provide an articulated reasoning with some rational underpinning to support the conclusion of obviousness as required by the Supreme Court in *KSR Int'l v. Teleflex Inc.* 127 S. Ct. 1727 (2007). Rather, the Examiner merely states that including the list of features admittedly not present in the reference relied upon would be "performed readily and easily." Such reasoning is evidence that the Examiner has impermissibly used, in hindsight, Applicant's claim as a template to pick and choose from among various features to arrive at the claimed invention. Furthermore, the Examiner cites that to include the admittedly missing

features would not require "undue experimentation" or "risk unexpected results." Thus, the Examiner has apparently confused standards for enablement (undue experimentation) and exemplary arguments for non-obviousness (unexpected results) for a rational basis supporting the conclusion of obviousness.

For at least the reasons set forth above, the Examiner has failed to make a prima facie case of obviousness for claims 24, 29 and 30. Therefore, the rejection thereto is improper and must be withdrawn. Claims 25-28 each depend from and add features to claim 24. Therefore, for at least the reasons set forth above with respect to claim 24, the rejection of claims 25-28 are likewise improper and must be withdrawn.

The Examiner has rejected claim 31 under 35 U.S.C. §103(a) as allegedly unpatentable in light of Buonocore in view of Thangaraj. Applicant traverses this rejection for at least the reason that the Examiner has failed to make a prima facie case of obviousness for claim 31. For example, claim 31 depends from claim 30. As discussed above, the Examiner has failed to make a prima facie case of obviousness for claim 30 using Buonocore. The Examiner's reliance on Thangaraj fails to cure the deficiencies of Buonocore. As such, for at least the reason set forth above with respect to claim 30, the Examiner's rejection of claim 31 is likewise improper and must be withdrawn.

**CONCLUSION**

Having addressed each of the foregoing objections and rejections, it is respectfully submitted that a full and complete response has been made to the outstanding Office Action and, as such, the application is in condition for allowance. Notice to that effect is respectfully requested.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Date: **November 12, 2009**

Respectfully submitted,

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